## REMARKS

The Official Action dated January 24, 2005 has been carefully considered. The Applicant requests the Rejection be withdrawn, since the remarks are sufficient to place this application in condition for allowance. Accordingly, reconsideration is respectfully requested.

In the Official Action, claim 4 was rejected under 35 U.S.C. §102(b) as being anticipated by Chemical Abstract 87:63008. The Examiner asserted that the chemical abstract teaches use of the claimed prostaglandin in a pharmaceutical formulation as a bronchodilator.

However, Applicants submit that the composition of claim 4 is not anticipated by and is patentably distinguishable from the teachings of the cited chemical abstract. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, the cited chemical abstract discloses the synthesis and bronchodilator activity of DL-16,16-trimethylene prostaglandins. On the other hand, claim 4 is directed to a composition for the treatment of glaucoma and ocular hypertension. The composition comprises a therapeutically active and physiologically acceptable amount of 15(R,S)-16,16-trimethylene $PGE_2$, or an alkyl ester thereof, or a pharmaceutically acceptable salt thereof, and an ophthalmologically-compatible vehicle. Additionally, the composition is adapted for topical application to the eye. Applicants find no teaching or suggestion in the cited chemical abstract relating to a composition containing a prostaglandin in combination with an ophthalmologically-compatible vehicle, or relating to a composition adapted for topical application to the eye.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of the cited chemical abstract to teach the combination of a prostaglandin as presently claimed and an ophthalmologically-compatible vehicle, and the failure of the cited chemical abstract to teach a composition adapted for topical application to the eye, the cited chemical abstract fails to disclose each and every element set forth in claim 4. Thus, the chemical abstract does not anticipate claim 4 under 35 U.S.C. §102.

The Examiner has asserted that Applicants have alleged criticality to the different use of the claimed composition, rather than a difference in the composition. However, the composition defined by claim 4 comprises not only the recited $PGE_2$ compound, but also an ophthalmologically-compatible vehicle. Additionally, the composition is adapted for topical application to the eye. In contrast, the

cited chemical abstract provides no teaching relating to an ophthalmologically-compatible vehicle, or a composition adapted for topical application to the eye. One skilled in the art will recognize that the disclosure of a particular compound does not inherently disclose a composition adapted for topical application to the eye, or the compound in combination with an ophthalmologically-compatible vehicle. Thus, Applicants are not relying on an intended use of the composition of claim 4 to distinguish over the cited chemical abstract, but rather on the components and properties of the claimed composition. It is therefore submitted that the composition of claim 4 is not anticipated by the cited chemical abstract under 35 U.S.C. §102, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 7-11 and 18-23 were rejected under 35 U.S.C. §102(b) as being anticipated by the Stjernschantz et al U.S. Patent No. 5,296,504. The Examiner asserted that Stjernschantz et al teach the use of the claimed prostaglandins in a pharmaceutical formulation for the treatment of glaucoma.

However, Applicants submit that the composition defined by claims 7-11 and 18-23 are not anticipated by and are patentably distinguishable from the teachings of Stjernschantz et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

Claims 7-11 and 18-23 are directed to methods of treating glaucoma or ocular hypertension in a subject's eye for a period of at least six months, while reducing melanogenesis. According to independent claim 22, the method comprises contacting the surface of the eye with an effective intraocular pressure reducing amount of a therapeutically active and physiologically acceptable prostaglandin analog which is a selective agonist for $EP_1$ prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof, any melanogenesis which is caused by the method of treatment being reduced as compared with that obtained by a method of treatment in which a prostaglandin analog which is not a selective agonist for $EP_1$ prostanoid receptors is employed. Thus, the present methods provide improvement over chronic treatment methods, i.e., those lasting greater than six months, employing a prostaglandin or analog which is not a selective agonist for $EP_1$ prostanoid receptors.

As noted above, numerous prostaglandin compounds are covered by the generic formula which Stjernschantz et al disclose. However, Applicants find no specific teaching by Stjernschantz et al relating to prostaglandin analogues which are selective agonists for $EP_1$ prostanoid receptors, or relating to any improvement obtained by use of such compounds in a chronic treatment method as

presently claimed. In fact, as noted above, commercially available prostaglandins such as 13,14-dihydro-17-phenyl-18,19,20-trinor-$PGF_2$ alpha, which is the free acid of latanoprost, the active ingredient of Xalatan, and 16-phenoxy(3-trifluoromethyl)-17,18,19,20-tetranor-$PGF_2$ alpha, which is the free acid of travapost, the active ingredient of Travatan, are prostaglan FP receptor agonists, rather than selective agonists for $EP_1$ prostanoid receptors.

Further, Applicants find no teaching by Stjernschantz et al relating to a method of treating glaucoma or ocular hypertension in a subject's eye for a period of at least six months, while reducing melanogenesis. Particularly, Stjernschantz et al provide no teaching that melanogenesis can be reduced or avoided in such a chronic treatment method by administering a prostaglandin analog which is a selective agonist for $EP_1$ prostanoid receptors. Thus, Stjernschantz et al do not anticipate claim 22, or claims 7-11, 18-21 and 23 dependent thereon, under 35 U.S.C. §102, *In re Robinson, supra*. It is therefore submitted that the rejection of claims 7-11 and 18-23 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §102 and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

The Examiner rejected claims 7, 9, 10, 11, 22 and 23 under 35 U.S.C. §112 first paragraph, as not being enabled. The Examiner stated the specification only enables certain prostaglandin analogues which are selective agonists for $EP_1$ prostanoid receptors which are capable of treating glaucoma or ocular hypertension. The Examiner goes on the allege the specification does not enable any person skilled in the art to which it pertains to use the invention commensurate in scope with the these claims. Applicant respectfully disagrees. MPEP 2164.01 states "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. A patent need not teach, and preferably omits what is well known in the art." "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." It is submitted that the Applicant's specification is enabling since the test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The Applicant's specification (Applicant's specification page 7) provides that the prostaglandin analogue is derived from PGF or PGE type and goes on to provide that a prostaglandin of the general type found

on page 8 of Applicant's specification is envisioned. Applicant's specification also goes on to exemplify those prostaglandins which fall under the general formula (Applicant's specification page 12-22), in addition to providing general schemes to preparing the claimed compounds (Applicant's specification page 26-28) and numerous references related to the same (Applicant's specification page 29-30). In conjunction with the specific embodiments and references provided, the general formula found on page 8 provides a finite recognizable class of compounds of sufficient support to enable a skilled chemist to make compounds within the scope. Additionally, Applicant's specification goes on to describe a method of identification of prostaglandin receptors (page 9 of Applicant's specification).

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §112 and places the present application in condition for allowance. Therefore, it is respectfully requested that the Examiner reconsider and provide an early allowance as requested.

## CONCLUSION

In light of the foregoing amendment and remarks, Applicant respectfully submits that this application is now in condition for proper examination. Applicant invites the Examiner to telephone the undersigned attorney if there are any issues outstanding that have not been addressed to the Examiner's satisfaction.

There is no need to petition for a one-moth extension of time, since response to the Office Action was due Sunday April 24, 2005. However, since April 24, 2005 fell on a Sunday, Applicant has until Monday, April 25, 2005 to file a response. If the Applicant is in error, Applicant petitions for a one-month extension of the due date for responding to the Office Action dated January 24, 2005 to our Deposit Account No. 500329. Response to the Office Action is submitted herewith.

Respectfully submitted,

Date: **April 25, 2005**

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